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Appl. No. 10/010,242  
Paper dated February 4, 2004  
Reply to Office action of October 10, 2003

### **REMARKS/ARGUMENTS**

This amendment is in response to the office action dated October 10, 2003.

Applicant submits herewith a request for extension of time and appropriate fee. Claims 1- 32 were originally presented in the application. Claims 5, 8, 9, 15, 18 and 19 are canceled by this amendment. Consequently, claims 1-4, 6, 7, 10-14, 16, 17 and 20-32 are still pending.

Applicant hereby amends the specification at page 6, line 7 to correct a number, changing "Figs. 1 and 1" to "Figs. 1 and 2". The amendment adds no new matter.

### **Claim Rejections**

The Examiner rejected claims 1-15 and 31 as being anticipated by Lee et al or Legerton et al. Applicant traverses the rejections.

A reference only anticipates a claim if it discloses every element of the claim. *Scripps Clinic & Res. Found. v. Genentech, Inc.* 927 F.2d 1565, 1576 (Fed. Cir. 1991). Applicant respectfully points out that the cited references do not teach each and every element of the claims, particularly as amended.

With regard to independent claim 1, neither Lee et al nor Legerton et al disclose a lens for use with a dilated pupil having an annular, substantially clear center area of greater than approximately 4 mm in diameter and a light restricting area surrounding the clear area having an inner margin and an outer margin and uniform opacity across the expanse of the light restricting area.

As an initial matter both Lee et al and Legerton et al disclose lenses that are used to correct vision. By contrast, the instant invention is designed to decrease the amount of light entering a dilated pupil. Consequently, the relative dimensions and configuration of the center areas of the cited lenses and the claimed lenses, particularly in combination with the specific designs of the surrounding mask areas of the respective lenses, are important distinctions. It is important for the Examiner, when looking at the references, to consider the teachings of the entire reference. When considering the distinctions between the claimed lenses and the cited lenses, along with the entire teaching of the references, it is apparent that neither reference includes the all of the elements of the instant claims.

Claim 1 provides for a lens including an annular clear area and an annular light restricting area surrounding the annular clear area, the light restricting area having a uniform opacity across its expanse. In effect, this claimed structure produces a clearly demarcated light blocking around a dilated pupil. The instant device is intended to be used to reduce the amount of light entering a dilated pupil. Use of the instant invention with the claimed size of the clear opening, and the clearly demarcated light-blocking zone of uniform opacity produces the effective of a normally sized, age-related pupil.

On the other hand, Lee et al teach an annular mask having "soft edge" formed by gradually decreasing the transmissivity radially from the center area or an area of variable transmissivity formed by "petals" (col. 9, lines 14-22). Lee et al's device is a

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vision-correcting device, using an annular mask to reduce diffraction distraction created by a vision correction device for ametropia and presbyopia. This soft reduction in diffraction is created by the variable density tinting applied to the edge of the correcting optics portion of the device. The diffraction distraction also can be reduced by the irregularly shaped demarcation, i.e. the petals, with result in a non-annular center zone. Legerton et al tout the halo elimination properties of their invention as having partially opaque zones or at the outer edge of the opaque ring resulting from the tapering of the opacity. (col. 2, lines 47-50).

As the Examiner notes, Lee et al teach a clear center area of approximately 2 to 4 mm in diameter. Pinhole contact lenses, also used for vision correction, have clear center apertures up to 4 mm (Lee et al, col. 1, lines 28-36). Legerton et al suggests a lens having an aperture of greater than 4 mm (col. 3, lines 5-10), but only in combination with the specific mask region that does not have uniform opacity across the expanse of the mask area or that has tapering opacity. Consequently, neither of the references shows a clear area of greater than 4 mm in diameter in combination with a clearly demarcated light blocking area of uniform opacity. Because neither of the references include each and every element of claim 1 and the claim is allowable over the art.

Claims 2-4, 6 and 7 depend from claim 1, further defining the invention. Since, the cited references do not disclose each and every element of claim 1, it follows that

neither reference teaches each and every element of the claims that depend from claim

1. Therefore, claims 2-4, 6 and 7 are allowable.

Independent claim 10 is allowable over the references for reasons similar to those stated above in regards to claim 1. Neither Lee et al nor Legerton et al teach each and every element of claim 10. Neither reference teaches a lens having an annular clear zone of greater than 4 mm in diameter surrounded by an annular light-blocking zone having uniform opacity. Hence, claim 10 is allowable over the references. Claim 11 depends from independent claim 10, further defining the invention, and also is allowable over the references.

Claim 12 provides a method of restricting the amount of light that enters the dilated pupil of the eye including the step of placing an artificial lens over the pupil of the eye, the artificial lens including the combination of a substantially clear center zone of greater than 4 mm in diameter and an adjacent light restricting zone of uniform opacity across the width of the zone, and positioning the recited clear zone over the pupil so as to allow a restricted amount of light into the eye. Neither of the cited reference discloses a method or restricting light including each and every step of claim 12. Hence, claim 12 is not anticipated by either reference and is allowable. Claims 13 and 14 depend from claim 12 and also are allowable.

Claim 31 is allowable over the art of record since neither Lee et al nor Legerton et al disclose the recited means for positioning over the pupil of the eye to allow the

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passage of light or the recited means for restricting the light. These elements of claim 31 are written as means for performing specified functions in accordance with 35 U.S.C. §112, ¶6. These elements should be construed to cover the corresponding structures and materials described in the specification. Neither Lee et al nor Legerton et al disclose those means. Therefore, the references do not disclose each and every element of the claim and the claim is allowable.

The Examiner rejected claims 16-30 and 32 as being anticipated by Stoyan. Applicants traverse the rejections on the grounds that Stoyan does not disclose each and every element of the claims.

It should be understood that Stoyan is a corneal molding device used to reduce myopia, developed for the purpose of reshaping the human cornea. Stoyan's lens is supposed to be applied to a normally healthy, myopic eye for a period of time of continued wear and then removed, resulting in a reshaped cornea and improved vision. Because it is designed to actually change the shape of the cornea, Stoyan's lens includes a central zone that has a radius of curvature that gradually increases from 4 mm to 20mm (col. 3, lines 18-22). Hence, the radius gradually changes from steep to quite flat.

The invention of claims 16-30 is designed to be applied to the corneal of the eye that has been surgically altered to create an artificial lens of the appropriate refractive power used to improve vision without physically altering the shape of the underlying

cornea. The front surface of the lens of the present invention provides a more regularly shaped refractive surface while the back surface is designed to accommodate the misshapen cornea, generally a cornea that has been flattened. The instant lens provides a relatively normal reflective outer surface, while the back or inner surface fits the misshapen cornea. The lens of the present invention is not intended to physically alter the shape of the misshapen cornea.

The invention of claims 16-30 includes Zone A, which is relatively flat, which facilitates the positioning of the lens on a corneal that is relatively flat, for example a cornea flattened from corneal surgery. Notably, because Zone A is intended to fit a relatively flat corneal surface, Zone A has a uniform curvature, generally between approximately 9.2 mm to 10.5 mm. The lens of the present invention also includes a steeper, Zone B, adjacent Zone A and, as provided in claims 28 and 29, for example, the curvature of Zone B is such that Zone A is one(1) diopter flatter than the adjacent zone. Zone B forms a transition area between the surgically flattened cornea and the surrounding corneal surface.

Claim 32 is allowable over the art of record since Stoyan does not disclose the recited means for conforming the lens to the shape of a flattened cornea without physically altering the shape of the cornea. This element is written as means for performing specified functions in accordance with 35 U.S.C. §112, ¶6. Consequently, the Examiner must look to the corresponding structures and materials described in the

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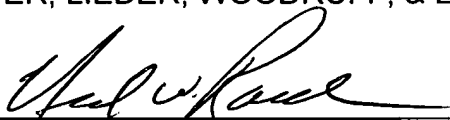
specification for performing the recited function. Stoyan does not include those means. Hence the reference does not disclose each and every element of the claim and claim 32 is allowable.

In summary, because Stoyan does not disclose a lens having a generally flat central zone of uniform curvature and a surrounding zone having a lesser radius of curvature that, when placed on the cornea, results in an artificial surface of appropriate refractive power that does not alter the physical shape of the underlying cornea, as generally required by the claims, it does not anticipate claims and they are allowable over the reference.

In view of the foregoing, Applicants respectfully request reconsideration and allowance of the claims and passage of the case to issue.

Respectfully submitted,

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